LEISEGANG
The Colposcope Company

Installation and Operating Instructions for

L E I S E G A N G
Colposcopes and Accessories

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Edition November 2012

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Objective Determination

Colposcopes are employed in gynecological examinations for the magnified, contactless examination of the external feminine genital organ (vulva, vagina, portio).

However, they can also be employed for magnified, contactless examination of other external organs.

In the case of colposcopes, there is the possibility to connect photographic recorders - according to features and model - for evaluation and subsequent documentation.

Colposcopes are used exclusively for diagnostic purposes and thus correspond to §3, Para. 1 of the MPG, in accordance with the requirements on a medical product.

So that you become completely acquainted with the functionality and operation of your colposcope and become familiar with the system, we recommend you to read these directions for use carefully before the first use of your device.

In case of any questions, we are glad to remain available for you at any time:

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1. Important general references

1.1 Preliminary notes

With the purchase of a LEISEGANG colposcope, you have decided on an advanced product which was developed and has been continuously improved in cooperation with practicing gynecologists, in order to become better adapted to the requirements of modern treatment technology.

Experience, precision and continuous manufacturing optimization, has enabled LEISEGANG Feinmechanik-Optik GmbH to become the leading manufacturer of colposcopic precision instruments, with the largest product range of colposcopes in the world.

1.2 Determination-Appropriate Use

Colposcopes and their accessories may be employed only for gynecological examinations and for the magnified viewing of organs, which are visible and accessible, without direct patient contact from outside.

They may be employed only with the mounts, sources of light, flash equipment and accessories, provided for this purpose by the LEISEGANG Company.

The restrictions, which are stipulated in the directions for use, are to be considered.

The device is designed for application in medical practices and/or clinics and for the environmental conditions prevailing there.

According to the stipulations of the MPG, colposcopes may be operated only by those persons who have been instructed in the expert handling of the device.

The proper installation and maintenance of the device are absolutely vital prerequisites for the use of the colposcope.

The user has to check the functional-stability and proper condition of the device before every application

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1.2.1 Indications for use

A colposcope may be helpful in the following situations.

1. Major abnormality on pap smear.
2. Persistent minimal abnormality on pap smear..
3. Abnormalities of squamous or columnar cells..
4. Persistence of an inflammatory appearance of the smear despite adequate treatment..
5. Presence of keratinised cells suggestive of leukoplasia.
6. Symptoms of metrorrhagia, in particular contact bleeding..
7. Abnormal appearance of cervix or vagina by naked-eye examination.
8. Monitoring after treatment of dysplasia, regardless of treatment method..
9. Evaluation after exposure to diethylstilbestrol (DES) or related drugs during embryogenesis.
10. Evaluation of anogenital condylomatosis.
11. Evaluation of vulvo-perineal bowenoid papulosis.
12. Preoperative evaluation before genital-traGt surgery: hysterectomy, treatment of genital prolapse, cervicovaginal plastic surgery, ete.
13. Lesion noted on routine gynecologic examination.

1.2.2 Contra - Indications for use

The colposcope is a device for viewing the body from a distance and is not intended for patient contact.. Because of this there are no contraindications for use of a colposcope.

1.3 Symbols

Caution!

Reference

Installation

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1.4 How to read this operating instructions

These have the objective of explaining the structure and the operating mode of the colposcope in several stages, to make understandable and technically feasible the installation of the individual subassemblies, up to the finished system, as well as to put the users into the situation where they are able to eliminate small faults themselves, since the technical interdependencies are understood.

The subdivision of these instructions corresponds to the structure of a colposcope. First the head, then the mount, then accessories, electrics, maintenance and safety are reviewed. In order to facilitate their reading and understanding for you, we have structured the page so that the drawings always appear on the left double page and the text always appears on the right.

The inside edge of the right-hand page is exclusively reserved for important key words (cf. key word register at the end), symbols and provides sufficient space for your personal remarks, in order to rapidly find (again) particularly important points.

The meaning of the symbols is as follows:

Caution: Please make absolutely sure that you consider the information and details provided at this location, in order to avoid damage to persons and to the device.

References: Here, reference is made to certain behavior and procedures during the installation and adjustment of the device or individual device subassemblies, such as the change of light intensities, filter insertions, fuse replacement and similar.

Installation: The delivery of the goods dispatched from LEISEGANG Feinmechanik-Optik GmbH always includes the tools needed for the installation, such as screwdrivers, Allen keys and similar.

2. Important Notes on Safety (PLEASE READ THESE CHAPTER URGENTLY FIRST)

Before you start operation of the colposcope into, please make yourself familiar with the following safety regulations and consider these during the entire period of employment of the device:

2.1 List of Warnings

1. The colposcope is equipped with a safety mains cable and may be connected exclusively to a protective grounded plug socket only.

2. Do not employ any extension cords.

3. Never adjust or cover over the transformers or other subassemblies. This can lead to overheating and damage to the device.

4. The power supply units for the illumination lamp should be switched on for safety reasons only for 10 minutes per hour (Not necessary for LED-lighting). A device switched on durably can be overheated in certain situations.

5. Employ exclusively those mounts which have been provided to you, together with the LEISEGANG colposcope or have been manufactured by LEISEGANG Feinmechanik-Optik GmbH.

6. Do not hang any additional objects on the colposcope or on parts of the mount which are not explicitly planned for that.

7. Do not lean on the device.

8. Do not operate the device in an explosive-endangered environment.

9. Defective cables or plugs are the causes of electrical accidents and fires. Renew defective cables immediately or call an authorized technician.

10. Power supply units with damaged cases are not allowed to be used any longer. They must be exchanged by LEISEGANG immediately

11. The mains cable may never be removed at the cable connection end but always at the plug socket only.

12. Before connecting the power supply to the device, it must be checked whether the mains voltage and frequency agree with the information on the label.

13. Do not roll the device over deep-pile carpets or over objects which are on the floor (cables,

hoses).

14. Never set up or operate the device on rough or tilted surfaces.

15. Except for the components described in these directions for use, the device may be opened exclusively by LEISEGANG-trained personnel only, since high-voltage live parts are present in the device or in the subassemblies.

16. LEISEGANG isn't liable for damages resulting from improper use of their products or contraventions against safety notes mentioned above.

17. Disposal: Devices produced by LEISEGANG and defective parts as well must be disposed professionally only according to the valid laws and standards in the operator’s country.

3. Certifications

3.1 CE Certification

The device is tested according to the specifications of the European Directive 93/42/EWG, dated 14th June 1993, and fulfills the necessary standards concerning the MPG Medical Products Law. All devices, which are manufactured by LEISEGANG Feinmechanik-Optik GmbH, belong to Class 1 of non-invasive products, according to Appendix IX of EU Guideline 93/42/EWG. The colposcopes are checked for compliance with the basic requirements according to Appendix I of Guideline 93/42 EWG and are provided with the CE mark which indicates agreement with the legal stipulations.

A declaration of conformity from LEISEGANG Feinmechanik-Optik GmbH, as well as full test documentation and protocols, are available on request.

3.2 UL Certification

CLASSIFIED UL XXXX

LEISEGANG colposcopes model 1DS, 3MS, 3MLS
WITH RESPECT TO ELECTRIC SHOCK
FIRE, AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL 60601-1

LEISEGANG colposcopes and colposcopic accessories are certificated according to the strict US-American market laws for medical devices. LEISEGANG products meet the requirements of UL 60601-1. They are labeled with UL mark.

3.3 Quality management

LEISEGANG Feinmechanik-Optik GmbH company has been established a quality management system according to ISO 9001 since 1995, upgraded to ISO 13485 in January 2004. Regular internal auditing is the key for continuous improvements. Monitoring by authorized external auditors guarantees the agreement with the respective international standards.

During the whole manufacturing process LEISEGANG products are subjected to production accompanying quality controls.

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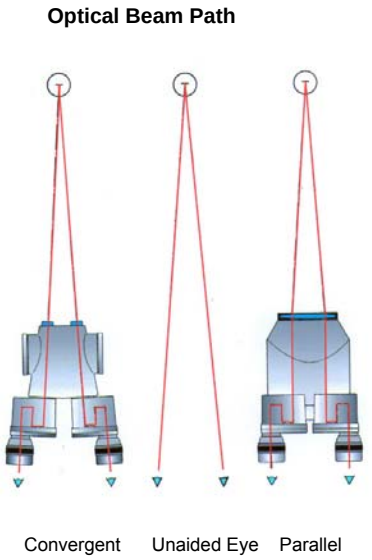
4. Short Product Overview

In the description of the different colposcope model series and types, certain terms and technical solutions are addressed, which, in part, are available from LEISEGANG as the only worldwide provider. In order that, during the consideration of later models, cross references and return references to other sections do not interrupt the continuous flow of reading, a few terms are explained at this point.

- Optimal treatment success depends directly on optimum examination results. It is vital that the colposcope supplies a three dimensional image, which represents, as best as possible, the protrusions, depressions and blood vessels on the subject of examination. All LEISEGANG colposcopes, from Model Series 1 to 3, have the same quality optics and all offer **stereoscopic viewing**.

- Each of the two eyepieces can be optimally adapted to the individual eye and possible defective visions can be corrected with a **compensation for ametropia** (defective vision) from +7 to -7, so that the operator can work with and without viewing aids.

- **Convergent viewing beam paths** correspond to the natural viewpoint and - in contrast to parallel mode - focus very exactly on one predefined point (see diagram). The individual images of both eyes are placed over each other and automatically supply a spatial image, while instruments, which work in microscopic mode, always presuppose a short adaptation phase for the eyes, in order to provide convergence of the parallel individual images for a spatial viewpoint. With an average processing number of 20 - 40 colposcopic examinations per day, the selection of the correct examination device is a very important decision, also from the point of view of ergonomics to avoid tiring activities at work.



- If **colposcope heads and colposcopes** are referred to in the following text, then the term colposcope head always means only the actual examination instrument, while the colposcope describes the entire basic device with all accessories, from the mount, through the power and light source, up to the mains cable.

- LEISEGANG colposcope heads are further distinguished according to **model series and type**. In total, 3 different series, with various model types, exist for the most varied of tasks. For unambiguous identification, every device head bears a punched five-digit serial number, as well as type identification. The identification begins with a digit and, according to colposcope type, up to four more alphabetic characters. Every alphabetic character has its

own meaning, which provides information about the features of the colposcope head. Differentiation is as follows:

D = Rotary drum change-over for observation magnification
M = 7.5/15/30x magnification, forphopto- video colposcopes
V = Video colposcope with integrated camera
L = Photo colposcope, without electronic flash
W = Convenient 45° inclined oculars
S = Small magnification set 3.75/7.5/15x

- The colposcopes of the **Series D and M** are equipped with a rotary drum changer for three magnification stages. The scales with the magnification change are 1:2 in each case and basically result in another, unmistakable image. In detail, the following magnifications are available: 7.5/15/30x or 3.75/7.5/15x.

- In the case of the photo colposcopes of the **Series M**, three magnifications are also available for photography: 7.5/15/30x.

5. Guarantee

Provided that nothing else has been agreed on in writing, LEISEGANG Feinmechanik-Optik GmbH gives a guarantee of freedom from defects, corresponding to the respective state of the art and the device type or subassembly, for the devices manufactured by it in the Berlin factory, for a duration of 2 years from delivery date, to the first user.

Excluded from this are exposure, power and light-guide cables, lamps, fuses and other consumption materials. However, LEISEGANG Feinmechanik-Optik GmbH guarantees the full functionality capability of these on delivery.

If, in spite of quality control at the factory, faults occur on the device or subassemblies, this must be communicated immediately by the customer after their discovery to LEISEGANG Feinmechanik-Optik GmbH in writing and/or a complaint immediately made to the carrier about transport packaging damage.

LEISEGANG Feinmechanik-Optik GmbH will carry out repairs immediately, according to the technical requirements, by means of replacement or repair of faulty parts, without consideration of the costs that are necessary for the purposes of repair at a later stage.

A claim to replacement delivery does not exist.

The guarantee does not include the removal of damages, which have arisen due to

- A fault not indicated by the customer or
- The customer has not given the chance for the repair to be carried out immediately after request or
- The device or subassemblies have been handled incorrectly or
- The device or subassemblies have been repaired by third parties without explicit written permission from LEISEGANG Feinmechanik-Optik GmbH,
- Repair experiments have been undertaken or
- Care and maintenance operations were not carried out or
- The customer has not followed the specifications concerning the handling, maintenance and care of the device or the subassemblies, in accordance with the directions for use.

LEISEGANG Feinmechanik-Optik GmbH can provide no guarantee for faults, which have arisen through inappropriate treatment of the device or subassemblies, as well as for consequential damage to the device or subassemblies that has occurred due to faults in the electricity at the operation location and similar circumstances which have occurred in the area of the device user.
If other parts are added or connected to the device or subassemblies, without written consent from LEISEGANG Feinmechanik-Optik GmbH, or parts are removed, then the guarantee is rendered invalid with instant effect. This applies also in the case of removal of the serial number or the type plate, incorrect handling or willful destruction.
Natural wear on movable articulated links, springs, pull-out parts, painted surfaces and similar, are excluded from the guarantee.

The guarantee for LEISEGANG colposcopes is 2 years.

We hold spare parts for 10 years

6. Colposcopes

6.1 Equipment overview, installation and operation

At this point begins the directions for the actual use and installation of your device. Please first check for damage the outside of the transport packaging, and then the devices or subassemblies supplied.

The following chapters give a step by step account of the relevant testing, installation, operation and security references, as well as the correct locations to which you can refer if reason for complaint exists.

If, at this point, obvious defects should exist already, please immediately refer to your dealer or to LEISEGANG Feinmechanik-Optik GmbH, under the numbers indicated below.

6.2 Scope of delivery and testing of the supplied goods

The scope of delivery of a complete LEISEGANG colposcope basically always includes at least the following four different items:

1. The colposcope head
2. The mount with special part set (special installation equipment etc.) for the fixed attachment to the examination chair (B) or to a 5-wheel spiderbase (A);
3. The power and light source, i.e. transformer or cold light projector;
4. The accessories, i.e. cables, spare lamps, tools, fitting instructions etc.

Possibly associated with the scope of delivery:

5. Additional appliances, such as photographic and video cameras, adapters and external devices such as monitors, computer etc.

This 5-item sub-division corresponds roughly to the structure of these Installation and Operating Instructions. Please note, however, during the assembling of the device or devices, that the mount is always assembled first, then the power and light source and finally the colposcope head with accessories.

6.3 Model 1E light

This colposcope Model 1E light is a standard colposcope with restricted features in handling. All optical features are the same as colposcopes with higher performance.

Model 1E light

This standard colposcope fulfill the basic requirements of lots practicing gynecologist. Clear functions, ergonomic handling and the preparation for the possibility of later retrofitting of imaging systems and micromanipulators for laser applications (available only through laser manufacturer), characterize this series. Against all other LEISEGANG colposcopes this model has no horizontal and vertical fine adjustment. Only the inclining function is given.

6.3.1 Hold adjustment for inclining

If the colposcope will not hold the inclining position you have to adjust the inclining hold force with this screw.

6.4 Model 1E & 1D & 1DW

The Colposcopes of Model 1 series includes LEISEGANG popular standard colposcopes with precision fine adjustments in horizontal and vertical direction, green filter and high performed optics.

Model 1E

Model 1D

Model 1DW

FEATURES

Model 1E

- 15x standard magnification
- Inbuilt 24V/18W LED Lighting

Model 1D

- 3 magnifications drum changer (7.5x/15x/30x). S-version with 3.75x/7.5x/15x
- Inbuilt 24V/18W LED Lighting

Model 1DW

- 3 magnifications drum changer (7.5x/15x/30x)
- Inbuilt 24V/18W LED Lighting
- Comfortable 45° inclined ocular optics
- **WITHOUT GREEN FILTER**

6.5 Model 3MV & 3MVW & 3ML & 3MLW

The Model 3 series are LEISEGANG's popular Photo and Video colposcopes with precision fine adjustments in horizontal and vertical direction and high performed optics.

Model 3MV

Model 3ML

Model 3MLW

FEATURES

Model 3MV

- With integrated Camera (USB-2.0 **OR** Y/C / S-Video Output) and synchronic 3 magnification for observation
- 3 magnifications drum changer (7.5x/15x/30x).
- Inbuilt 24V/18W LED Lighting

Modell 3MVW

Like Model 3MV but with comfortable 45° inclined ocular optics; No picture

Model 3ML

- 3 magnifications drum changer (7.5x/15x/30x). S-version with 3.75x/7.5x/15x
- Inbuilt 24V/18W LED Lighting
- External camera adaptation with synchronic 3 magnification to observation

Modell 3MLW

Like Model 3ML but with comfortable 45° inclined ocular optics

6.5.1 Model 3MV Interfaces

Model 3 MV comes with two different Interfaces.

- USB 2.0, which have to be connected to PC or Laptop. This interface supplies the integrated camera via USB cable.
- Y/C respectively S-Video interface can connect directly to the S-Video input of monitors, without interconnection of PC or Laptop. A special power supply supplies this camera with power. See Chapter 8.3.1

Model 3MV with USB or S-Video interface

Model 3MV with S-Video Camera and Monitor with S-Video Input

6.5.2 Camera adaptation

You can connect different kinds of cameras at LEISEGANG Photo Colposcopes and Video Adapters. Depending on the type of camera you need a special tubus. The kind of tubus can be a T2 Adapter, Video Adapter or Camera adapter in several sizes. If you have got the wrong adapter, please contact us.

Take the Video Tubus

and a Camera

Connect both by using the threaded joint

All Photo-Colposcopes (except Model 3MV) owns a so called camera port to take the camera. This device is attached below the colposcope head.

Push this combination into the camera port, plug in the USB cable and connect the other end to a computer.

You have to use cameras without objective lens only.

6.6 General Adjustments

Most of adjustments are the same for all colposcopes. Normal Adjustments means the adjustment at daily work like focusing, choosing of magnification or turning the green filter in.

6.6.1 Rough height adjustment

Every colposcope head is packed into a solid plastic bag on delivery, in order to remain protected against dust and dirt. The head always represents the last part which is mounted. It should remain in the bag until final assembly.

Take the colposcope head from the bag and guide the chrome-plated insertion tube into the previously fixed assembled mount (cf. drawing on the opposite page) and fix it at the standard height appropriate for the colposcopy, with the aid of the black clamping button. In this case, it is to be ensured that the insertion tube is inserted sufficiently far into the mount, in order that the instrument can be fixed sufficiently solidly.

With this knob you can adjust the height of colposcope in a rough position for your convenient posture. The fine adjustment you will do by with the fine adjustment handle explained under 6.6.1.

6.6.2 Vertical & Horizontal fine adjustment

The both most used adjustments are the horizontal & vertical adjustments of the colposcope head. Use the vertical adjustment for convenient posture the head in height and the horizontal adjustment for focusing the object.

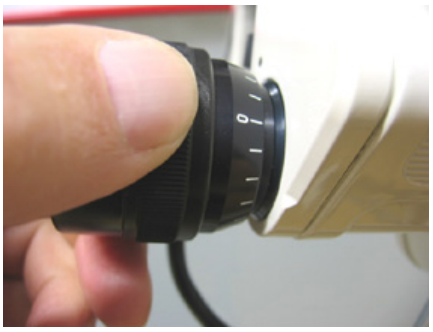
1 Turning this handle results in a vertical movement of the colposcope **1'**.

2 Turning this handle results in a horizontal movement of the colposcope **2'**. You will use this handle to focus the image.

3 Inclining this handle results in a there and back inclining of the colposcope **3'**. You will use this handle to focus the image.

6.6.3 Compensation of ametropia

Every LEISEGANG colposcope offers the opportunity of compensation of ametropia for both eyes in a range of +7 to -7 diopter.



6.6.3.1 Focusing the Leisegang Colposcope

- The working distance of a properly focused Leisegang colposcope is about 300 mm or 12 inches. A sheet of paper, at 11 inches, is a good starting reference for length between the colposcope and the object of focus.
- Move the scope head to the center of the traveler using the fine focus adjustment handle.
- Set both oculars to zero (20/20 vision) and set the step magnification dial to 15x. (The clinician begins an exam at the lowest magnification; however, once you focus at 15x, you will be in focus at 7.5x and 3.75x).
- Adjust the interpupillary distance (eye separation) to your face, until a single image is visible. This is done by adjusting the binoculars wider or narrower.
- Looking through the left eyepiece at the targeting reticules only, rotate the left ocular eyepiece until the two double circles are clearly focused. When this is achieved, do not touch this eyepiece for the remainder of the exam.
- To adjust gross focus, move the colposcope back and forth until you can see the test object clearly with your left eye in the left eyepiece.
- Rotate the right ocular until you can see the object clearly with your right eye.
- At this point the colposcope is par focalized. During this exam and all that follow for a particular user there would be no need to touch the two eyepieces.
- View using both eyes. If needed, move the colposcope back or forth in relation to the subject and adjust the fine focus. With the colposcope par focalized you will have about 300 mm (12 inches) of working distance.

6.6.4 Magnification Changer

About the magnification changer you can choose the right magnification / view area for your observation.

Field of view in mm

Magnification 7.5x/15x/30x	Magnification 3.75x/7.5x/15x (S-Version)
46	76
23	38
11.5	19

Using Magnification Changer

Mag 7.5x ➔ **Mag 15x**

6.6.5 Green filter

With the knob on the right side of the scope you can turn the Green filter in and out.

6.7 Help Yourself

All LEISEGANG Colposcopes and Accessories are shipped as well adjusted. Over the years and by daily using something can become unadjusted. This chapter will give an introduction to help yourself. Special adjustments you have to do not often than 1 time in a year like rough height hold adjustment for inclining etc.

6.7.1 Fine height adjustment

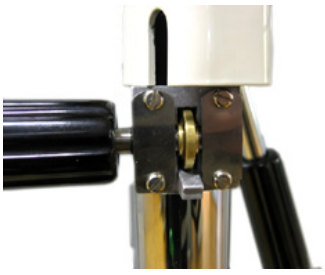
Sometimes the head will run very slow out of its height position and you have to readjust the fine adjustment very often.

In this kind you can help yourself by running the rough adjustment procedure.

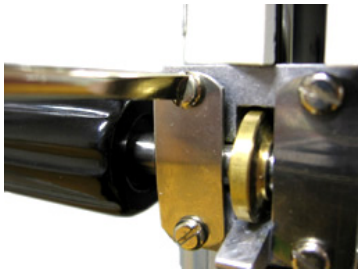
Please do it by the following steps:

1.) Bring the scope in a higher position

2.) Shift the metal cover with type label up



3.) Tighten the screws a little bit until it is fixed enough



4.) Shift the cover down to the origin position

6.7.2 Hold adjustment for inclining

If the colposcope will not hold the inclining position you have to adjust the inclining hold force with this knob.

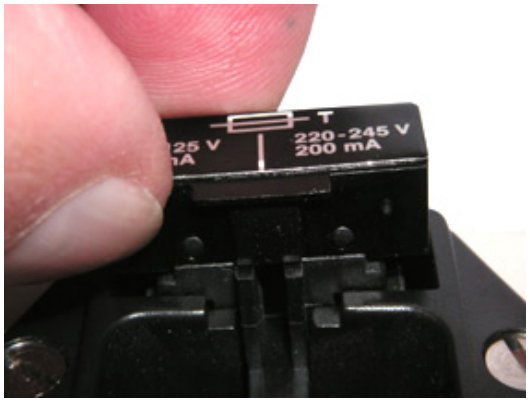
6.7.3 Lamp change

In November 2006 LEISEGANG has introduced first time it's colposcopes with LED Lighting. Since this time the demand to this kind of illumination has increased extremely. LEISEGANG decided to offer their colposcopes up from November 2008 with LED lighting only. While using the LED lighting a lamp change is not necessary anymore.
See chapter 8.1.

6.7.4 Fuses

Fuse holders are located at the power supply of illumination unit and cold light projector. In each case, 2 fine-wire fuses are located in a fuse holder. After switching off the device and unplugging the power supply from the device, the fuse holder can be pulled out from the casing with a screwdriver. The fine-wire fuses can be withdrawn and replaced. For this purpose, they are removed from the fastener and inserted again. Then the mains cable is plugged in again. The fuses cannot be replaced without unplugging of the power supply. It is to be ensured that new fuses indicate the same values as the defective ones (time-lag T).

Main Plug with Fuse Holder



Pull out the fuse holder

&

Change the fuses

7. Stands

All LEISEGANG stands are characterized by the highest levels of quality and stability for daily employment in practices and clinics. The decision however, whether the colposcope is to be used in a mobile mode on several examination chairs or fixed assembled on one, must be fully checked before ordering, since the respective stand forms can clearly differ, according to location and operation purpose.

The following paragraphs deal with the stand types available at LEISEGANG:

- *Swing Stand;*
- *Balance-o-Matic Stand;*
- *Upright Stand;*

The installation of the stand is the first thing to be implemented with every new setting of a colposcope, since the fixed position of the stand must first be ensured before the expensive examination device is attached.

Please follow the individual stages of the fitting instructions for the respective stand form in the numerical sequence indicated, in order to avoid damage to the device or individual subassemblies.

7.1 Swing Stand

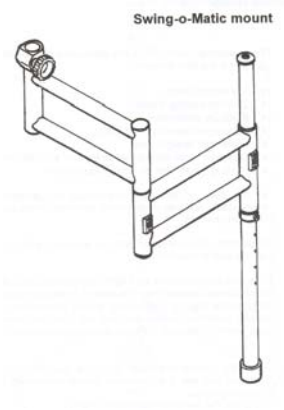
The Swing Stand is the most widely sold Stand type worldwide. It consists of two right-angled tubular frames, which enable a horizontal radius of 60 cm with almost 360° pivoting capability.

The fixed attachment of the Swing Stand is basically possible onto every gynecological examination chair that is equipped with round or rectangular tube frames, or, however, has a prepared area for the attachement of colposcopes.

In addition, the Swing Stand also builds up to a 5-wheel mobile spider base, which offers free but stable mobility.

Swing Stand with heavy spider base

7.1.1 Installation of Swing Stand

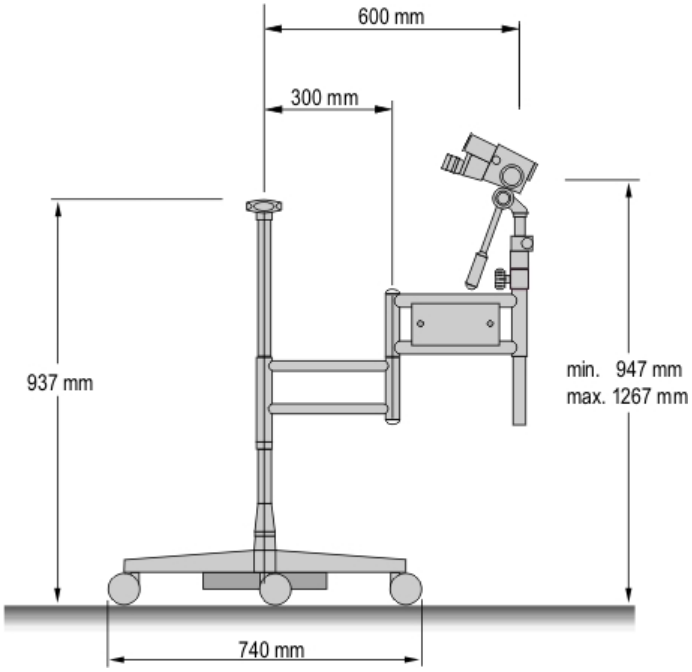


See 7.2.1 Installation of Balance-o-Matic Stand

The Installation of both stands is nearly the same.

As a next step the illumination unit shall be assembled, see Chapter 8.

7.1.2 Dimensions

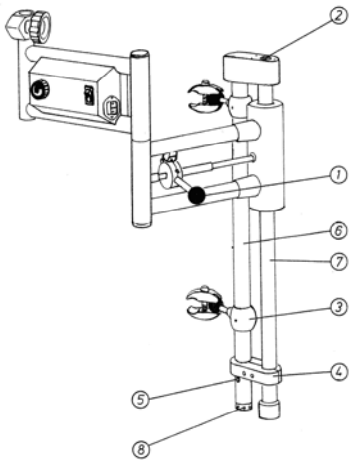


7.2 The Balance-o-Matic Stand

The LEISEGANG Balance-o-Matic Stand offers a maximum of comfort with the greatest ease of operability. A two-stage brake arm (1) at the lower Stand frame enables the fixed setting of the Stand, as soon as the operator has carried out the rough adjustments in the horizontal and vertical direction.

7.2.1 Installation of Balance-o-Matic Stand

The Balance-o-Matic Stand is attached to the examination chair in exactly the same way as the Swing Stand. The exact vertical alignment with the aid of the built-in water level (2) is very important. If the form of the legs of a chair should require that the lower clamp (3) must be attached above the cross connection (4), as represented, the cross connection is loosened and removed with the Allen key supplied. The clamp (3) is displaced upwards with the slit casing over the protection pin (5) and the cross connection is secured again. In this case, it is to be ensured that the protection pin (5) remains accessible for changing the spring loading.



For the purposes of weight compensation, an extension spring is located in the external Stand tube, whose loading must be adapted to the weight of the colposcope head, as well as to additional subassemblies, by means of a control ring (8). For the adaptation, an Allen key or screwdriver is inserted into one of the holes of the ring; this is then rotated a little to the right against the spring force and the protection pin (5) is pulled out. For safety reasons, a second Allen key or screwdriver should be at hand, since the slow loading or unloading of the spring requires a reinsertion of the lever into the control ring.

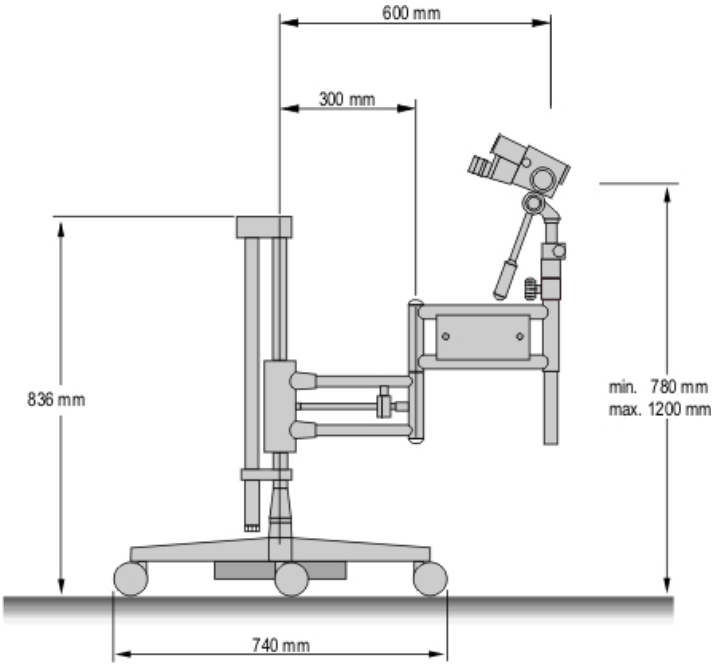
Caution: By removing the protection pin, the entire weight of Stand, colposcope head and accessories is now supported at the lever inserted in the ring! If this slides out, the spring in the tube is unloaded and the entire colposcope will suddenly collapse. For this reason it is recommended to fix the Stand in the center position before the removal of the protection pin and only then to begin with the settings, or however, a second person helps by supporting the Stand arm.

The ring (8) is now rotated against or with the spring loading until the above-mentioned balanced suspension status of the colposcope is achieved. The ring is arrested again by the reinsertion of the protection pin. Here, the ring is rotated a little back and forth until a hole for the protection pin is found.

With this, the Balance-o-Matic Stand would be firmly connected.

As a next step the illumination unit shall be assembled, see Chapter 8.

7.2.2 Dimensions



7.3 Upright Stand

The Stand tube must be inserted with the lower ends (cf. drawing on the opposite page) into the spider base and tightened up with a locking bolt. There are no further settings possibilities for this Stand, except that 2 of the 5 rollers can be set with a brake.

7.4 Installations

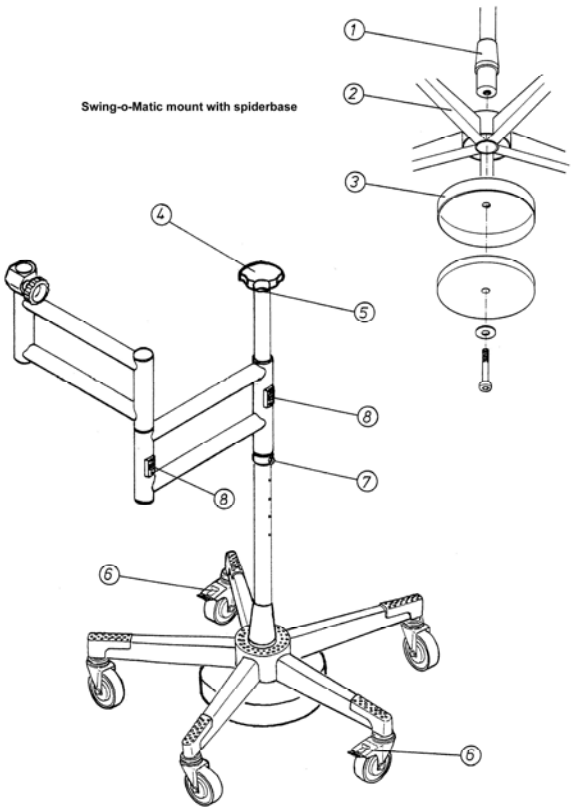
7.4.1 Installation of Swing Stand on mobile 5-wheel spider base

1. The stand upright (1), equipped with a black cone, is inserted into the corresponding receptacle of the 5-wheel spider base (2). The locking weight is screwed from below securely onto the column, with the aid of the delivered hexagon socket screw and the spacing washer, where the cap (3) is placed securely over the locking weight in order to conceal this optically.

2. The star-shaped handle (4) is used for the guiding of the Stand during rolling. After intermediate insertion of the fan washer, it is screwed into the column (5) and tightened up well. Two of the five rollers have a locking facility (6) against unintentional movements of the system.

3. The Stand has been preset in the factory to a predetermined height. In order to change this, the small locking pin (7) at the supporting ring of the lower Stand frame is pulled out slightly (after slight lifting), and brought to the required height by engagement in one of the existing boreholes. Please ensure that the pin audibly engages, in order to exclude a slipping of the Stand to the lowest position and possible injuries.

4. With this, the Swing Stand is firmly connected. For fine adjustment of the horizontal pivot movement you can tighten or loosen pressure screws (8) with a coin at two points so that the movement is more or less smooth-running.



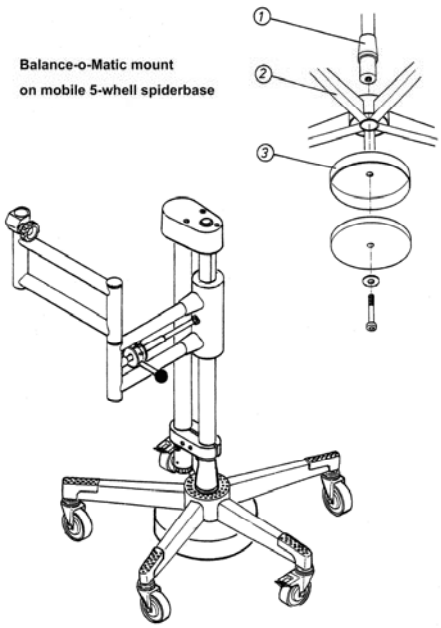
If a Swing Stand, initially mounted to the examination chair, is to be used in the future with a 5-wheel heavy spider base, it is absolutely necessary that the stronger stand upright must be reordered for roller Stand with conical setting.

7.4.2 The Balance-o-Matic Stand on mobile 5-wheel spider base

The stand upright (1), equipped with a black cone, is plugged into the corresponding receptacle of the 5-wheel spider base (2). The locking weight is screwed from below securely onto the column, with the aid of the delivered hexagon socket screw and the spacing washer, where the cap (3) is placed securely over the locking weight in order to conceal this optically.

Two of the five rollers have a locking facility (6) against unintentional movements of the system.

If a Balance-o-Matic Stand, initially mounted on the examination chair, is to be used in the future with a heavy 5-wheel spider base, the necessary retrofitting set with the conical insert must be reordered.



As a next step the illumination unit shall be assembled, see Chapter 8.

7.4.3 Fixed attachment onto the gynecological examination chair

Swing or Balance-o-Matic stands are mountable to gynecological chairs and tables

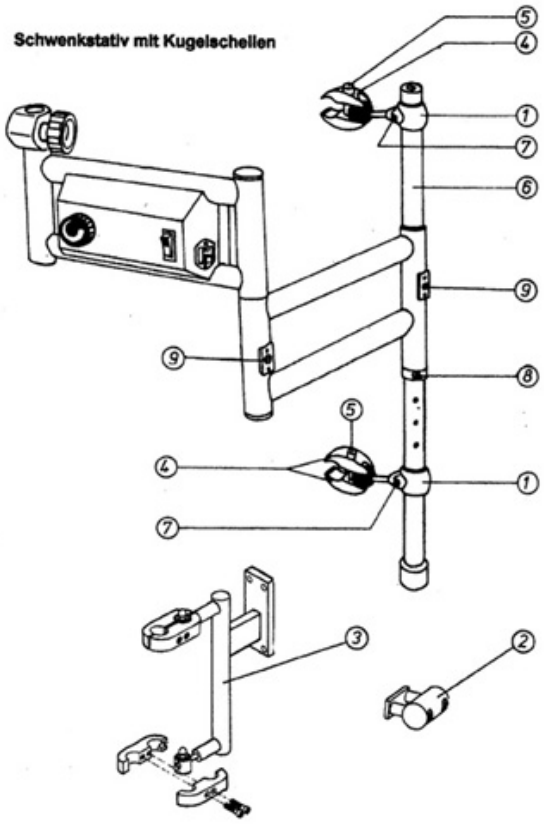
With the utilization of assembly aids and/or special equipment, the corresponding fitting instructions are supplied by the chair manufacturers if the fixing is directly addressed by the chair manufacturer. In the case of delivery of special equipment and/or assembly aids from LEISEGANG, you receive a separate fitting instruction for the corresponding chair model in each case.

It is important that the Stand is attached as solidly as possibly with the lower frame on the examination chair, so that a completely rigid connection results. Only in this way it is guaranteed that the weight of the examination instrument is permanently held in case of full loading and steady positioning of the colposcope is enabled during the examination.

Different installation sets are available for this, which are in part provided by the chair manufacturer or by LEISEGANG Feinmechanik-Optik GmbH. We would be glad to give you information about this, under the telephone number noted down in the foot note, if you give us the manufacturer and chair type.

The individual installation sets are designated as follows :
Ball-type clamps (1);
Assembly aids (2);
Special equipment (3).

- In the case of installation with ball-type clamps, it is necessary to connect these with the vertical Stand tube as far above and as far below as possibly (cf. drawing on the opposite page). The sticked side of the clamp half (4) grips around the existing chair tube, while the other side is clamped around the ball. In no case should the surface of the legs of a chair be protected against the uneven gripping of the clamps by adhesive tape or similar, since otherwise the connection will not have a solid grip.



- The clamping bolts (5) are tightened with the aid of the Allen key and should face toward the side that can be easily reached later with the key. The shell halves are screwed together, first of all, only loosely in order to find the most favorable position of the Stand during the subsequent colposcopy.

- Please ensure the stand upright (6), with the built-in water level, is aligned completely vertically. Only when this alignment has been completed and the later working position has been determined, are the bolts of the clamps tightened up.

- Following this, the Stand upright tube is clamped with the aid of the bolt (7) in the painted clamp and secured against rotation.

- The Stand has been preset in the factory to a determined height. In order to change this, the small locking pin (8) at the supporting ring of the lower Stand frame (after slight lifting), is pulled out slightly and brought to the required height by engagement in one of the existing boreholes. Please ensure that the pin audibly engages, in order to exclude a slipping of the Stand to the lowest position and possible injuries.

- With this, the Swing-o-Matic Stand is firmly connected. For fine adjustment of the horizontal pivot movement you can tighten or loosen pressure screws (9) with a coin at two points, until the guide action is easy and pleasant for the physician.

The Balance-o-Matic Stand is attached to the examination chair in exactly the same way as the Swing Stand. The exact vertical alignment with the aid of the built-in bubble level is very important.

As a next step the illumination unit shall be assembled, see Chapter 8.

8. LED Lighting

Every LEISEGANG Colposcope (except Cold-Light Models) is available with LED Lighting.

LED stand for Light Emitting Diode, this light is produced in an electronic process in semiconductor without substantial heat losses.

LED Colposcopes are equipped with an LED unit. This consists of a heat sink unit with LED and the condenser lens optics. The light of LED is just as bright, as from Cold-Light Projectors. Thus the brightness exceeds it from standard Colposcopes with 20W halogen bulb clearly. In addition it provides another light character for a more plastic impression, than the lamps used in the past.

LED unit

The used power supply unit weights 500g only and possesses a power consumption of maximum 18W.

With a life span of more than 20,000 operation hours this lighting can work a whole working life without exchanging the LED unit. If this lighting fails sometimes please check the power supply unit first. The exchange of the LED unit should be accomplished by an electrical specialist only or directly at Leisegang factory in Berlin.

8.1 LED Power Supply

The used power supply is physical similar with the 30 Watt Halogen power supply, but with a weight of 500g only and a reduced power consumption of 18W only.

- Power Supply 18W for LED-illum-ination. A similar device is available for Model 3MV-YC, which will supply (12V) the integrated S-Video-Camera or an external PAL-Camera with S-Video interface.

8.2 Supplying Model 3MV-YC

For driving Models 3MV-YC a very similar power supply is available. This device supplies the LED and additionally the integrated camera via the same cable. You will find the type label in chapter 13.1.5.

This device can supply external PAL-Cameras with an inbuilt via a 12V / 150 mA low voltage plug. No additional power supply is necessary.

8.3 Mounting of Power Supplies

For Swing- and Balance-o-Matic Stand the case of power supply will be mounted between the two pipes of the upper frame.

The Power Supply can be mounted on the Swing or Balance-o-Matic Stand between the two tubes of the upper frame. For Upright stands you have to use two clamps.

The mounting to the Upright Stand happens by using two mechanic clamps at the standpipe.

Front **Back**

Be careful while unscrewing the 4 screws. The case will fall in two parts. Before unscrewing the case, unplug the unit from mains/primary voltage.

At the end of power supply unit you will find the two plugs for primary and secondary voltage. The primary voltage plugs holds two fuses. Plug in the lamp cable from colposcope head and turn clockwise until locked.

The illumination unit is approved according to the relevant DIN IEC Standard and carries the serial number on the label.

The illumination unit may be operated only with alternating current with the frequency and voltage indicated on the label. It is not approved for operation in areas with explosion danger.

SAFETY ADVICE

The illumination unit should be switched on for safety reasons for only 10 minutes per hour. A device switched on durably can overheat in certain situations.

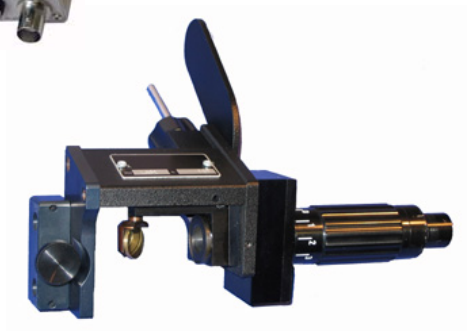
9. Accessories

LEISEGANG offers several kinds of accessories

- **Video Adapters**

- **Cameras**

- **Micromanipulator**



- Photo Tubes
- Picture Management Software
- Chair Mounts
- Spider Bases

The following sections will give further information for the **bold printed items**.

9.1 Video Adapters

All LEISEGANG colposcopes can retrofit by video adapters via a mounting plate which can be easily mounted with 3 screws at the front of the scope. The video adapter by itself can be mounted very simply without any tools.

LEISEGANG Video Adapters are available for one and three magnifications.

Standard magnification is 15x. The three-mag adapters have 7.5x/15x/30x (in S-Version 3.75x/7.5x/15x).

9.1.1 Mounting Video Adapters

1. Fastening of VA mounting baseplate

Fasten the mounting baseplate with three screws

2. Alignment of video adapter fasten area

Put the mounting plate and video adapter fasten area one above the other

3. Fixing of video adapter

Push both pins of video adapter fasten area into Mounting baseplate and tighten the knurled screw

4. Video adapter is ready to use

9.2 Cameras

LEISEGANG offers different kind of cameras for capturing pictures to be stored on computer or for showing live pictures on monitor.

PAL Camera with S-Video Interface

Compact High Solution Camera with USB 2.0 interface

PAL cameras are showing the normal TV resolution

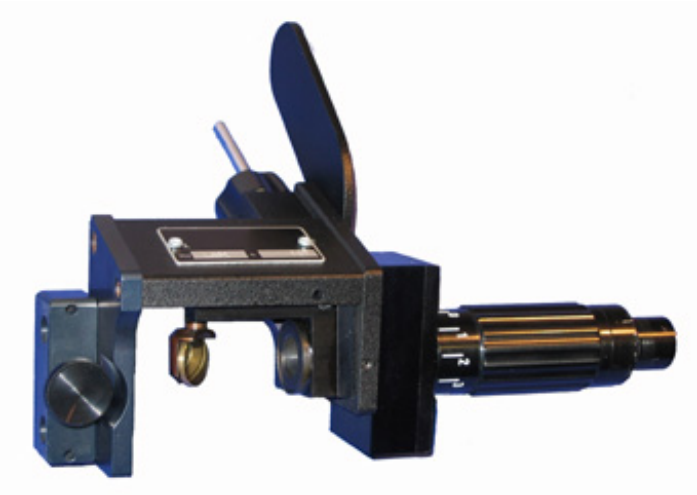
High resolution cameras have resolutions from one to several mega pixels

SLR cameras without objective lenses are possible to connect and use. The disadvantage of these cameras is: they are unable to create a live video picture.

9.3 Micromanipulator

LEISEGANG Micromanipulator provides the possibility to connect several CO2 Lasers models to the colposcope.

Several mounting base plates are available for mounting on the different colposcope models.



The respective laser supplier is responsible for the instruction and starting up of the micromanipulator.

The micromanipulator is intended for CO2 Laser with an output power up to 100 watt.

Mistakes of the central adjustment and their elimination

When the positioning beam HNE-red is fine-focussed, it may occur that it does not correspond with the rings in the eyepiece. To a certain extend, this does not cause disadvantages for the surgeon. Important is, whether the working beam corresponds with the search beam. In order to assess, you should not proceed from the fact, whether the central point of the beam is located in the central point of the eyepiece but the search beam and the working beam have to be in correspondence. This can be achieved by locking the control rod in position Ring to n 1". The positioning beam is observed and the wOrking beam is shortly switched on. If there is a fault of correspondence of the two beams it has to be eliminated at the articulated arm. If the fault is found in the central point it can be adjusted.

Adjustment of laser beam centre

After loosening the lock screws, the screws of the adjustment plate have to be correspondingly turned by means of the annexed hexagon driver (Allen) 2 mm that a movement of the laser beam into the central point is achieved. In order to reduce disturbing movements of the whole device

while doing so, all links of the swing or the balance-o-matic arms should be put into a locked position or the device should be supported by the chair or something else.

During the adjustment you should also have a look through the eyepiece to control possible unintended shifting of the middle position.

After adjustment, has been carried out, the lock screws have to be fastened up to the limit stop without any force in order to secure the adjusted position.

In a normal position the adjustment plate is situated parallel to the upper plate of the chassis and the distance is 1 mm. If all screws should be removed by mistake, more screws are still inside for security.

10. Care and maintenance

The colposcopes are devices which are simple to maintain and care for. No great expenditure of effort is needed to keep your device in a tidy and functional condition. Nevertheless, we recommend to consistently carry out the measures described below, in order to guarantee the life of your device and trouble-free functioning on a long-term basis.

10.1 Colposcope head

The colposcope head should be wiped with a moist cloth at regular intervals (Attention: moist, not wet!). In particular, liquid splashes on the front panel can occur with the employment of the device and these should be wiped off. If the optics of the head are also soiled, they should be cleaned with commercially available lens cleaning papers. Also moist spectacle cleaning cloths are suitable, for example. Standard detergents can be employed with the usual dilution. Please do not employ strong detergents or concentrated alcohol under any circumstances for the cleaning of optics. This would lead to irrevocable damage to the optically coated lens surfaces.

Please never use corrosive materials or strong cleaning materials on the casings or on the optics. Such materials lead to permanent damage of the painted surface of your device and/or scratch the lens coatings of the optics. This leads to considerable loss of quality of the entire visual system.

For the protection of the colposcope head and, in particular, the optical system, we recommend to place a dust cover over the colposcope head after every use, in order to minimize dust contamination of the device.

10.2 Stands

Similar to the colposcope head, the Stands should also be sometimes wiped with a moist (not wet!) cloth. Standard detergents can be employed in usual dilution. Further maintenance work on the Stands is not necessary.

10.3 Accessories and external devices

In the case of accessories, video adapters and photographic adapters should be mentioned in particular, which should be wiped externally, if required, using a slightly moist cloth. Optics, which is easily accessible from outside, should be cleaned with optics cleaning agents, analogous to the optics of the colposcope head.

Please do not attempt to clean the optics in the interior of video and photographic adapters, since these can be easily knocked out of adjustment and/or damaged and so that a repair becomes necessary. In the case of soiling in the interior of accessories, please contact LEISEGANG Feinmechanik-Optik.

11. Replacement wear parts and technical service

11.1 Technical service

... before you dial our number in Berlin.

If you make use of the technical service of LEISEGANG Feinmechanik-Optik GmbH, however you first of all wish to have some information about a defect that has occurred, then we request you to give the corresponding serial numbers of the individual components over the telephone. These can be read off from the punched digits on the metal labels. In the case of the individual subassemblies, the labels are situated at the following locations:

- Colposcope head with standard and photo colposcopes (Series 1-3): At the insertion tube on the cap
- Transformer: On the reverse side of the operating controls.
- Video adapter: On the side.
- Micromanipulator: On the side.

Communication of the serial number speeds up the support
from LEISEGANG Feinmechanik-Optik GmbH.

In case of all questions concerning the service, please refer directly to us under the following address:
LEISEGANG Feinmechanik-Optik GmbH
Leibnizstr. 32
D - 10625 Berlin
GERMANY
Phone: +49 (0) 30 / 319009-0 Fax: +49 (0) 30 / 313 599-2
e-mail: info@LEISEGANG.de
http:\\www.LEISEGANG.de

11.2 Spare and wear parts

There is a dozen of relevant spare parts and not more than 3 parts the end user should have close by his own.

- ***Bowden cable Part Nb. B 141 for balance-o-Matic Stand only.***
- ***Fuses***
- ***Ocular shells***

11.2.1 Fuses

SEE CHAPTER 6.7 Help Yourself

12. Technical data and notes on safety

12.1 Control and maintenance

Quality controls are carried out for the devices of LEISEGANG Feinmechanik-Optik GmbH. However, the following recommendations are worth mentioning:

1.
Ensure that cables, light guides, cable releases and other cables are not too wound up. Unplug wound up connections and plug these back after unraveling.

2.
Ensure, in particular, that electric connections and mains cables do not indicate any external damage. Replace defective cables immediately.

3.
Occasionally ensure that the locking weight under the spiderbase has not loosened. Screw it back again if necessary.

4.
Ensure that mechanical adjustment devices are working smoothly and without error. In case of occurrence of problems, inform LEISEGANG Feinmechanik-Optik GmbH.

5.
Regularly check the steel pulling cable for wear.

12.2 Returns, complaints

Returns of devices or subassemblies may occur only after prior arrangement with LEISEGANG Feinmechanik-Optik GmbH. Please refer beforehand to our service, in order to arrange details of the procedure. Complaints about devices or subassemblies supplied by us are to be communicated to us immediately, with information of the serial number, the delivery date as well as the reason of the complaint. Please send your complaint in writing to the following address (Fax or e-mail is sufficient):

LEISEGANG Feinmechanik-Optik GmbH
Leibnizstr. 32
D - 10625 Berlin
GERMANY
Phone: + 49 (0) 30 / 319 009- 0
Fax: + 49 (0) 30 / 313 59 92
e-mail: info@LEISEGANG.de

Since, in the normal case, your device has been supplied through the medical-technical specialist shop.

13. Technical Data

13.1 Type plates

Except for stands, all LEISEGANG devices carry type plates. The contents of type plates show the product name, and the serial number. Electrical devices show the power data and additional information such as year of construction and CE or/and UL mark.

13.1.1 Colposcope head

This plate is located below the head.
It shows the Model Type (see chapter **15. ANNEX**) and serial number.

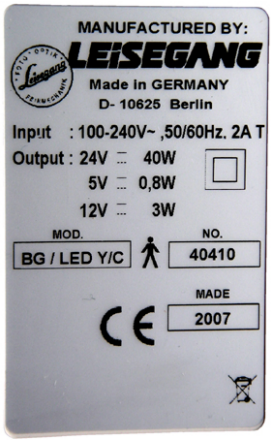
The serial number is important if you have any questions or complaints.

13.1.2 LED Power Supply

This plate is located on the front side of the power supply.

13.1.3 Power Supply LED with auxillary power plug

This power supply will be used for Model 3MV with Y/C (S-Video) interface or an external S-Video camera shall be connected. A maximum power of 12V / 150mA is available. An extra supply is not necessary.



13.1.4 Video Adapter

This plate is located below the head.
It holds the Model Type and serial number.

The serial number is important if you have any questions or complaints.

13.2 Classification

Classification according to MPG (and Guideline 93/42/EWG): Class 1

Application part

13.3 Safety Class

	Type	Safety Class
Illumination Unit	B	
LED Unit		

13.4 Environment Conditions

Use

Environmental Temperatur:	between +10 °C and +45 °C
Relative Humidity:	between 30% and 75%
Atmospheric Pressure:	between 700 hPa and 1060 hPa

Shipping & Storage

Ambient Temperature	between -20 to +70 o C
Atmospheric Pressure	50 kPa to 106 kPa

13.5 Dimensions and weights (all information approx.)

Standard colposcope head	3.5 kg
Swing-o-Matic mount	7.0 kg
Balance-o-Matic mount	9.5 kg
5-Wheel spiderbase with balancing weight	25.0 kg
5-Wheel spiderbase (light)	4.0 kg
Upright column	3.0 kg
Tilt-o-Matic stand	3.0 kg
30 VA Power Supply for 20W Halogen-Illumination	1,3 kg
LED Power Supply	0,5 kg
Bases for mounts (spiderbase)	65 x 65 cm

13.6 Electrical connections

Rated voltage: Please note information on label!	90V - 240V
Nominal frequency: Please note information on label!	50/60 Hz

13.7 Power Consumption

Power Supply 18W LED (LED Colposcopes only)	24 VA
Power Supply Y/C 24W LED (LED Colposcopes only) and eventually external supply of S-Video Camera 12V/150mA	24 VA

13.8 Fuses

Power Supply (Y/C Model also) LED 40W	
90 -240V	5 x 20 mm; 2A; T

13.9 Lamps

LED module with heatsink, LED and Condensor optic	24V / 18W

14. Leisegang Colposcopes EMC Compliance Information

- MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.

- Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT.

14.1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Leisegang Colposcopes are intended for use in the electromagnet environment specified below. The customer or the end user of Leisegang Colposcopes should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Enviroment- guidance
RF emissions CISPR 11	Group 1	Leisegang Colposcopes use RF energy only for it internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Leisegang Colposcopes are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

14.2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Leisegang Colposcopes are intended for use in the electromagnet environment specified below. The customer or the end user of Leisegang Colposcopes should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environmental - guidance
Electromagnetic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Leisegang Colposcope requires continued operation during power mains interruptions, it is recommended that the Leisegang Colposcope be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level. In this case 230 V.			

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environmental - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Leisegang Colposcope, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

[a]	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Leisegang Colposcope are used exceeds the applicable RF compliance level above, Leisegang colposcopes should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Leisegang Colposcope.
[b]	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

14.3 Recommended Separation Distance

Recommended Separation Distance between portable and mobile RF communications equipment and the model Leisegang Colposcope

The Leisegang Colposcope are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Leisegang Colposcopes can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Leisegang Colposcopes as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter **Watts**	Separation distance according to frequency of transmitter Meters		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{v_1}\right]\sqrt{P}$	**80 MHz to 800 MHz** $d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.1167	0.1167	0.2333
0.1	0.3689	0.3689	0.7379
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3789
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output rating of the transmitter in watts (W) according to the transmitter manufacturer.
For the Leisegang Colposcopes

v_1 = 3 Vrms

E_1 = 3 V/m

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

15. ANNEX

Type plate declaration

		Ocular View		Magnification			Adjustment		Illumination			Camera Interface		
Column		**1**		**2**			**3**		**4**			**5**		
	Model Description	**Straight**	**45°-Inclined**	**1 15x**	**D 7.5/15/30x**	**S 3,75/7.5/15x**	**Fine**	**Light Inclining only**	**LED**	**Halogen 20W**	**Fibre Optic 75W**	**None**	**USB**	**Y/C**
Code	**XXX**	**1**	**2**	**1**	**2**	**3**	**1**	**2**	**1**	**2**	**3**	**0**	**1**	**2**
Example 1	**1D**	**1**			**2**		**1**		**1**			**0**		
Example 2	**3MV**	**1**			**2**		**1**		**1**				**1**	

Example 1

Old	**1D-LED**
New	**1D-12110**

Example 2

Old	**3MV-LED USB**
New	**3MV-12111**